Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **THE WAVE 2 CASES IDENTIFIED IN EXHBIT A TO ETHICON'S MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY DR. DUNN PH.D, P.E.,

I. INTRODUCTION

Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., P.E., ("the Motion" or "Ethicon's Motion"), is fundamentally flawed. Ethicon's Motion not only ignores the opinions that are actually being offered by Dr. Dunn, but it purposefully confuses the issues and misstates the facts. Dr. Dunn is a chemical engineer with over twenty years' experience in device design and related fields. Dr. Dunn's report is separated into two sections: 1) Polymer Failure Opinions and 2) Product Design Opinions.

The Polymer Failure Opinions in his report are *unchallenged*. Ethicon only invents controversy by asking the Court to exclude opinions that are not contained in his report—specifically, that he should not be able to testify about how *in vivo* Prolene degradation occurs or if it leads to clinical harm. Dr. Dunn's report contains no description about how *in vivo* oxidation and degradation occurs inside the body nor does it connect that phenomenon to clinical outcomes. His report only describes the fact that Prolene's *in vivo* oxidation and degradation have been observed internally at Ethicon as well as in the peer-reviewed literature. Indeed, there

are many fact witnesses who have testified about the dozens of internal studies that have used SEMs, FTIRs, and other methods of polymer failure analysis that Dr. Dunn relies upon for his opinions—and there are just as many studies in the peer reviewed literature that support his opinions too.[1] Dr. Dunn's Polymer Failure Opinions will help the jury understand that Prolene is not an inert material and that the Ethicon researchers knew that fact very early on—the first half of his report, therefore, is relevant and reliable and should therefore be allowed at trial.

Similarly, Ethicon's Motion invents controversy when it attacks Dr. Dunn's Product Design Opinions. Ethicon's arguments there fail because they attempt to give priority to the guidelines suggested by the International Organization for Standardization ("ISO") for what a medical device risk analysis *should* contain instead of giving priority to the requirements *mandated* by the actual risk analysis that Ethicon chose to use for the devices at issue: the Failure Modes and Effects Analysis ("FMEA").

Importantly, Ethicon *never* challenges Dr. Dunn's expertise in using and evaluating FMEAs as they relate to product design and quality systems—and instead, it argues that he is unqualified to offer his opinions because he lacks expertise in biomaterials and medical devices. This argument would have merit if Dr. Dunn were opining on how *in vivo* degradation occurs or how clinical harm is linked to defects in Ethicon's mesh products, but his report contains nothing on either subject. Product design, risk analysis and quality control require that device performance is monitored and assessed in a multi-disciplinary group that would include individuals with expertise in medical devices and biomaterials, but Dr. Dunn does not need to have those credentials to know if the chosen systems are operating correctly. Indeed, there is an entire field of technical science behind Dr. Dunn's Product Design Opinions and Ethicon's Motion ignores it.

[1] Ex. A, Dunn Report; *see also* Ex. B, Dunn Reliance List

For example, Dr. Dunn's report states that the FMEA is a method of risk analysis, that it must describe every failure mode considered for a given product, and that it must be treated as a living document throughout the product's lifetime—those statements about the FMEA are unchallenged. Instead, Ethicon argues that the guidelines from the applicable ISO standards don't require the same things that the FMEA does—which while it is a true statement, it only works to confuse the issues in this case. Here, Ethicon chose to use the FMEA as the risk analysis for all of its medical devices—and the FMEA requires that it be a living document with all failure modes described—as such, Ethicon should have utilized the FMEA properly. Ethicon will have to explain it at trial why its risk analysis for the products at issue is lacking. Dr. Dunn's Product Design Opinions are valid and Ethicon is free to bring up any of its arguments to him on cross examination, but none of his opinions can be excluded under *Daubert*.

Moreover, Dr. Dunn's opinions and methodology have not changed since he was vetted to testify about Ethicon's mesh products in the *Huskey* litigation.[2] He has never been excluded in any Ethicon case and he should be allowed to testify in this Wave as well. Indeed, this Court has routinely held that experts with qualifications similar to Dr. Dunn's are permitted to offer general causation opinions based upon: (1) the peer-reviewed scientific literature, (2) their education and experience, and (3) their review of SEM images and other relevant evidence—and there is no reason why the Court should reverse its previous rulings (and the other progeny of *Daubert*) in the present case.[3]

II. STANDARD OF LAW

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be

[2] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D. W. Va. 2014)
[3] *Id*.

qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

The Court's focus in a *Daubert* inquiry should be solely on the expert's "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Notably, "the Supreme Court itself viewed *Daubert* as a *liberalization*, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996) (emphasis added). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.*

I. ARGUMENT

A. Dr. Dunn is qualified to offer his opinions.

Ethicon's arguments to exclude the testimony of Dr. Dunn misstate what his actual opinions are, they are not supported by any legal precedent, and they are undermined by the prior ruling of this Court. Indeed, Dr. Dunn has never been limited in any Ethicon case and he was permitted to offer his opinions in the *Huskey v. Ethicon* case where this Court held: "[an] expert's testimony must help the jury to 'understand the evidence or to determine a fact in issue.' Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O. Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is DENIED."[4] Dr. Dunn's opinions are relevant to the ultimate question of liability that the jury will be asked to decide, they are based on the peer reviewed literature, the scientific method, and are otherwise sound under FRE 702 and *Daubert*. They should not be excluded.

[4] *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014).

a.Dr. Dunn has expertise in Polymer Failure Analysis and the use of FMEAs.

Ethicon argues that Dr. Dunn is not qualified to render his opinions because he does not have the relevant experience in biomaterials and medical devices, but this mischaracterizes his opinions. Dr. Dunn's polymer failure opinions rely upon many fact witnesses who have testified about the dozens of internal oxidation studies that include SEMs, FTIRs, and other methods of polymer failure analysis that are part of the record in these cases—and there are just as many studies in the peer reviewed literature that support his opinions too.[5] Those opinions are beyond reproach and should not be excluded under *Daubert*.

Additionally, his device design opinions, which include a description of how to utilize an FMEA and how it plays a part in the overall quality system, are not challenged. Instead, Ethicon focuses its argument on his qualifications in medical device design and biomaterials, but these arguments fail. Indeed, Dr. Dunn's report states that as part of product design, the FMEA requires input from a multi-disciplinary team with several different areas of expertise; the Prolift product itself was assigned to have input from the Gynecare R&D Project Leader, a Design Quality Engineer, a Packaging R&D Engineer, a Medical Director, a Design Quality Engineer, an Operation Integration Project Manager, a Medical Affairs Manager, an Equipment Engineer, a Process Engineer, and a Quality Engineer.[6]

Dr. Dunn does not and could not possibly have the experience, training or education to qualify as an expert in all of those areas. He is an expert on polymer failure analysis and product design, which includes how to utilize the FMEA as part of a larger quality system. Ethicon's Motion fails with respect to his polymer failure opinions (because they are not challenged) and it fails with respect to his product design opinions because he does not need to be an expert in

[5] Ex. A, Dunn Report; *see also* Ex. B, Dunn Reliance List
[6] Ex. A, Dunn Report at 23

biomaterials or medical device design to have expertise in product design and the use and evaluation of the FMEA. His opinions are relevant and reliable and should not be excluded.

b. Ethicon confuses the issues by focusing on the ISO standards instead of the FMEA.

Ethicon's Motion makes the mistake of arguing that the ISO standards for how a medical device manufacturer's quality systems should operate, including its risk analysis, are somehow controlling and negate Dr. Dunn's opinions. To be clear, the ISO standards at issue are guidelines that describe what a medical device quality system *should* look like and what a medical device risk analysis *should* contain.[7] Those same ISO standards also recommend using the FMEA as the risk analysis for medical devices—and indeed, the FMEA is the only risk analysis that is used in all of the medical devices at Ethicon.[8]

The FMEA was developed in the 1940's and it remains the same whether it is used by NASA for the space shuttle or if it is used in the products at issue.[9] An FMEA is a step-by-step systematic safety analysis that is conducted by a multi-disciplinary team comprised of members having diverse and overlapping expertise for identifying all possible potential failure modes for the product at issue.[10] As a chemical engineer, Dr. Dunn has conducted FMEAs as a team member assigned to polymer failure analysis and he has years of experience in using and applying FMEA as a risk analysis.[11] These two areas of his expertise are undisputed.

Instead, Ethicon tries to manipulate Dr. Dunn's testimony into making it seem like he doesn't understand what kinds of testing the ISO standards suggest, but this only undercuts Ethicon's arguments as the record is clear that Dr. Dunn knows and understands what these ISO

[7] Ex. A, Dunn Report at 21-23
[8] Ex. A, Dunn Report at 21-23
[9] Ex. A, Dunn Report at 23
[10] Ex. A, Dunn Report at 23
[11] Ex C, Dunn CV

standards are.[12] The truth of the matter is that the FMEA is a recommended mode of risk assessment for medical devices by those same ISO standards—and everything suggested in those guidelines is part of the FMEA. The ISO standards do not control how a risk assessment operates—Ethicon does, and it chose to use the FMEA. As such, Dr. Dunn is qualified to opine about problems in Ethicon's quality systems as they relate to failures in utilizing the FMEA.

c. Dr. Dunn is qualified to testify about how the FMEA fits into Ethicon's quality systems and about how its FMEA failures affect the overall quality system.

Dr. Dunn is qualified to testify about how an FMEA is conducted as part of quality systems and about the failures that he observed in how Ethicon was utilizing the FMEA. Ethicon is wrong every time it argues that Dr. Dunn cannot evaluate an FMEA without being an expert in biomaterials and medical device design.[13] The FMEA stays the same, no matter what industry it is used in—it is intended to be a living document that requires input from the field into the quality system for every potential failure mode for the lifetime of the product at issue.[14] Ethicon is free to cross examine Dr. Dunn at trial and explain to the jury how it accounted for Prolene's oxidation and degradation outside of the FMEA, but that has never been explained before and it has no bearing on the relevance and reliability of Dr. Dunn's opinions. His opinions should not be excluded simply because Ethicon disagrees with them.

d. Dr. Dunn does not need to be an expert in biomaterials to assess the failures of the FMEA and how they can affect quality systems.

Dr. Dunn is qualified to testify about how an FMEA is conducted as part of quality systems and about the failures that he observed in how Ethicon was utilizing the FMEA. Ethicon

[12] Def's Brief at 5-7; See also Ex. D, Dunn deposition 11/2015 at 182-191
[13] See Def's Brief, generally.
[14] Ex. A, Dunn Report at 21-27

is wrong every time it argues that Dr. Dunn cannot evaluate an FMEA without being an expert in biomaterials and medical device design. The rules for the FMEA stay the same, no matter the industry.

B. Dr. Dunn's opinions are reliable.

a. Dr. Dunn is an expert on utilizing the FMEA, and ISO standards are not controlling under the FMEA analysis.

Ethicon argues that Dr. Dunn's product design opinions are unreliable because: 1) the relevant ISO standards do not require the use of an FMEA, 2) the ISO standards do not require the use of the term "oxidative degradation", and 3) the ISO standards do not mandate that the FMEA be updated with additional failure modes. But Ethicon is again creating issues where none exist. First, while it is true that the ISO guidelines do not require the use of the FMEA—Dr. Dunn's report makes clear that Ethicon does:

> "Ethicon uses the recommendations in ISO 14971 as guidance for its risk analysis for medical devices, including the use of the failure mode and effects analysis, but the use of the FMEA is also mandated by internal SOP to provide a "methodology for evaluating and analyzing risks resulting from potential failure modes, with the objective of eliminating or minimizing these risks to an acceptable level with the current state of technology."

Second, while the ISO guidelines do not require the use of the term "oxidative degradation", the FMEA requires it to be listed and assessed as a potential failure mode in this case and it is still not described in the FMEA today.[15] And while Ethicon argues that it has somehow taken oxidation into account, it is not addressed in the FMEA and the testing to assess oxidation as part of a pelvic mesh has not been produced nor is it referenced in Ethicon's

[15] Ex. A, Dunn Report at 27-31

motion.[16] Ethicon Motion actually points the Court to certain documents that it says Dr. Dunn is ignoring, but this simply not the case.[17]

The Court need only look at the text supplied in Ethicon's Motion from two internal documents to see that the Ethicon did no biocompatibility testing on the meshes at issue and instead relied upon the use of Prolene as a suture material; it states: "Raw materials are chemically unchanged—the Soft PROLENE resins utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh."[18] Similarly, the Motion points to Court to a document showing that a literature search was done to assess the loss of mechanical integrity postoperatively, but nothing about degradation or oxidation is stated there—it doesn't even state when the search was conducted and if it was done on mesh or sutures.[19] Nothing in the Motion shows that the proper testing was done with the female pelvic floor in mind nor does it show that the device's safety was monitored through the FMEA for the lifetime of the product. Again, if Ethicon wants to explain why it did not utilize the FMEA properly when patient safety is at stake, then it can do so at trial—but Dr. Dunn's opinions should not be limited simply because he is right. His opinions are relevant and reliable in this case.

Finally, Dr. Dunn's report states that the FMEA is a method of risk analysis and that it must contain every failure mode considered and that it must be treated as a living document throughout the product's lifetime—those statements are unchallenged. Instead, Ethicon argues that the guidelines from the applicable ISO standards don't mandate the same things that the FMEA does—which is a true statement, but it has nothing to do with the reliability of Dr. Dunn's opinions. Here, Ethicon chose to use the FMEA as the risk analysis for all of its medical

[16] Ex. A, Dunn Report at 21-27; Def's Brief, generally.
[17] Def's Brief at 12-14
[18] Def's Brief at 13
[19] *Id.*

devices—and the FMEA requires that it be a living document with all failure modes described—as such, Ethicon should have utilized the FMEA properly and it will have to explain to a jury why it did not.[20] Dr. Dunn's Product Design Opinions are valid and Ethicon is free to bring up any of its arguments to him on cross examination, but none of his opinions can be excluded under *Daubert*.

b. ISO Standards are not controlling over the FMEA.

As stated in Dr. Dunn's report, the applicable ISO standards describe how a risk analysis should look and it also recommends using the FMEA as a risk analysis for medical devices.[21] Everything addressed in the ISO standards for how a risk analysis should look is in the FMEA. Ethicon cannot argue that Dr. Dunn's opinions should be excluded because it did testing pursuant to ISO 10993, but just didn't include it in the FMEA. The requirements of the FMEA are controlling because Ethicon made it the SOP for its risk analyses.

In addition, Ethicon asserts that it did not need to test if or how Prolene's *in-vivo* oxidation would harm women implanted with vaginal mesh.[22] In doing so, however, Ethicon is simply disagreeing with, and not undermining the scientific reliability of, Dr. Dunn's opinions. Dr. Dunn fully agrees with every recommendation stated in the ISO standards at issue, but Ethicon's arguments fail to grasp the concept that the FMEA comports with every standard for a medical device risk analysis that is described in the ISO standards—which includes the need for any biocompatibility testing or analysis described in ISO 10993.[23]

What Dr. Dunn disagrees with is Ethicon's argument that the Prolene meshes used in these pelvic applications did not need further testing after Ethicon found oxidative degradation

[20] Ex. A, Dunn Report at 21-27
[21] Ex. A, Dunn Report at 21
[22] Def's Brief at 16
[23] *See* Def's Brief, generally.

occurring on Prolene *in vivo*.[24] Ethicon argues that these ISO standards caution that unnecessary testing should be avoided—but Ethicon is perfectly willing to implant these pelvic mesh products without understanding the effect that oxidative degradation has inside the female pelvis.[25] All of Dr. Dunn's well-supported opinions are in direct opposition to that argument. And itis not the Court's role on a *Daubert* motion to determine which side is correct. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999).

c. Dr. Dunn is not a medical doctor, and he is not trying to associate clinical harm with Prolene's *in vivo* oxidation.

Ethicon's argument that Dr. Dunn is not qualified to testify regarding the clinical complications associated with the Prolene in Ethicon's mesh products seeks to confuse the issues in this case. Dr. Dunn does not provide any opinions on the clinical harm of the oxidative process, or the results of the degradation process *in vivo*.[26] Dr. Dunn will defer to other experts to speak to the clinical complications of Prolene oxidation and degradation inside the body.

d. Dr. Dunn is not a biomaterials expert.

Similarly, as explained above, Dr. Dunn has not and will not hold himself out as a biomaterials expert who is capable of testifying about how the body reacts with and oxidizes Prolene meshes.

e. ISO 14971 is a standard not a mode of risk analysis.

As explained in Dr. Dunn's report, ISO 14971 is an international standard that describes how to create and maintain a risk management plan for medical device manufacturers, including the requirement that every medical device have a risk analysis to maintain its safety, Ethicon mandates that the FMEA be used for its risk management plan to properly function. Dr. Dunn is

[24] Ex. A, Dunn Report at 19.
[25] Def's' Brief at 15.
[26] *See* Ex. A, Dunn report, generally.

an expert on polymer failure, device design, risk management, and risk analysis—those opinions are never questioned in Ethicon's Motion. Instead, Ethicon argues that Dr. Dunn should have assessed the risk/benefit analyses for these products to properly assess the health of its risk management plan.[27] And although Ethicon is correct that a risk/benefit analysis is part of a risk management plan, the point has nothing to do with the issues present. Dr. Dunn's opinions are focused on how the FMEA risk analyses were not properly utilized and because of that, the risk management plan is not properly functioning.

C. Dr. Dunn's opinions are not unfairly prejudicial.

As explained above, in *Huskey*, this Court held that an "expert's testimony must help the jury to 'understand the evidence or to determine a fact in issue.' Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O. Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is DENIED."[28]

In an attempt to counter-act this established probative value, Ethicon simply argues that Dr. Dunn is wrong about the occurrence of oxidative degradation, and that he has not studied how much time it takes to occur.[29] First, Ethicon's assertion that Dr. Dunn is wrong, and oxidative degradation simply does not occur, is not the type of question that the Court should answer on a *Daubert* motion. *Westberry*,, 178 F.3d at 261. Second, with regard to the timing of that oxidative degradation, that question is, at best, a subject of cross-examination—it does not require the exclusion of Dr. Dunn's opinions. *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972 2014 U.S. Dist. LEXIS 92316, 4 (S.D. W. Va. July 8, 2014); *see also Pugh*, 361 Fed. Appx. at 456 (Any weaknesses in the underpinnings of an expert's opinion go to the opinion's weight, rather

[27] Def's Brief at 18-19.
[28] *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014).
[29] Def's Brief at 19-20.

than its admissibility). As such, neither of these arguments raise the type of "unfair prejudice" that would call for the exclusion of Dr. Dunn's opinions under Rule 403.

D. Dr. Dunn will not testify about Ethicon's state of mind.

Ethicon correctly points out that this Court has previously excluded expert testimony regarding a corporation's knowledge or state of mind.[30] Dr. Dunn does not intend to do so in these cases. However, as this Court has previously ruled: "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions."[31] Dr. Dunn only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining how the results of Ethicon's internal studies are consistent with his opinions in this case.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that the Court DENY Ethicon's Motion to Exclude the Testimony of Dr. Russell Dunn in its entirety.

This 8th Day of August, 2016 By: /s/ Edward A. Wallace

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[30] Def's Brief at 20
[31] *Huskey v. Ethicon., Inc.*, 29 F. Supp. 3d 691, 702-703 (S.D. W. Va. 2014).

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CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

By: /s/ Edward A. Wallace_____